

MEDICATION GUIDE

Infergen® (Interferon alfacon-1) Suspension for Injection

Read this Medication Guide carefully before you start taking Infergen (In-fer-jen). Read the Medication Guide each time you refill your prescription because new information may have been added. You should also make sure that the pharmacist has given you the interferon your doctor prescribed for you. The information in this Medication Guide does not take the place of talking with your doctor.

What is the most important information I should know about Infergen?

Infergen is one of the treatments used for some people who are infected with the hepatitis C virus (HCV). However, Infergen can have serious side effects that, in rare instances, may lead to death. Before starting treatment, you should talk to your doctor about the possible benefits of Infergen and its possible side effects, to decide if Infergen is right for you. While taking Infergen, you will need to see your doctor regularly for medical examinations and lab tests to make sure your treatment is working and to check for side effects.

The most serious possible side effects of Infergen include:

Mental health problems: Infergen may cause some patients to develop mood or behavioral problems. Some of the signs of these problems include irritability (getting upset easily), depression (feeling hopeless or feeling bad about yourself), or aggressive behavior. Some patients may have thoughts of hurting or killing themselves or other people or may attempt to do so. You must tell your doctor if you are being treated for a mental illness or had treatment in the past for any mental illness, including depression and suicidal thoughts. Former drug addicts may lapse back into drug addiction or overdose. You should tell your doctor if you have ever been addicted to drugs or alcohol.

Blood problems: It is not uncommon for patients to have a drop in the numbers of two types of blood cells (white blood cells and platelets). If these blood counts fall to dangerously low levels, it could lead to infections or bleeding.

Body organ problems: Some patients may experience problems such as lung problems (such as difficulty breathing or pneumonia), stomach pains or nausea and vomiting, and eye problems that can cause blurred vision or cause you to lose your vision.

You should call your doctor immediately if you develop any of these conditions:

- You become very depressed or have thoughts about hurting or killing yourself or others,
- You have trouble breathing,
- You have severe chest pain,
- You have severe stomach or lower back pain, bloody diarrhea or bloody bowel movements
- You have difficulty seeing,

- Your skin yellows,
- You become pregnant,
- High fever,
- You notice unusual easy bruising, or bleeding

For other possible side effects, please read the section "What are the possible side effects of Infergen" in this Medication Guide. (p. 4)

What is Infergen?

Infergen (Interferon alfacon-1) is one of the drugs used to treat adults with lasting (chronic) hepatitis C virus (HCV) infection. HCV is a liver disease that is caused by the hepatitis C virus and is spread by contact with the blood of a person carrying the hepatitis C virus. Most people who get HCV carry the virus in their blood for the rest of their lives. Most of these people will have some liver damage, but many do not feel sick from the disease. In some people, the liver becomes badly damaged and scarred. This is called cirrhosis. Cirrhosis can cause the liver to stop working.

Your doctor will tell you if the hepatitis C virus you have is resistant (e.g., type 1 virus) or easier (e.g., virus type 2 or 3) to treat and what the odds of success are with the treatments. In some patients that have received Infergen, the amount of the hepatitis C virus in the body was decreased to a level so low that it could not be measured by blood tests. Your healthcare professional may ask you to have blood tests to help determine how you are responding to your treatment.

It is not known if Infergen can cure HCV (permanently eliminate the virus) or if it can prevent liver failure or liver cancer that is caused by HCV infection.

There is no reason to believe that Infergen therapy alone or in combination with other treatments will prevent a person with HCV from giving another person the HCV infection.

Who should not take Infergen?

Do not take Infergen if you:

- Are pregnant or breast feeding or planning to become pregnant
- Have autoimmune hepatitis (hepatitis caused by your immune system attacking your liver)
- Had an allergic reaction to another alpha-interferon or are allergic to any of the ingredients in Infergen (see ingredient listing at the end of this Medication Guide).

If you have or have ever had any of the following conditions or serious medical problems, tell your doctor before you start taking Infergen:

- depression or anxiety
- sleep problems
- drug or alcohol addiction or abuse
- high blood pressure
- previous heart problems
- liver problems (other than HCV)

- autoimmune disease (where your immune system attacks your body's own cells) such as psoriasis, systemic lupus erythematosus, or rheumatoid arthritis
- thyroid problems
- diabetes
- colitis (an inflammation of the bowels)
- cancer
- hepatitis B infection
- HIV infection
- kidney problems
- blood disorders
- alcoholism
- taking a medication that suppresses your immune system

You should tell your doctor if you are taking or planning to take other prescription or non-prescription medicines or vitamin and mineral supplements and herbal medicines.

If you have any questions about your health condition or about taking Infergen, you should talk to your healthcare professional.

How should I take Infergen?

When you first start taking Infergen, you will be given the medication by a healthcare professional as an injection under the skin. If your doctor has determined that you or a family member or friend are able to give you Infergen at home, it is important that you learn how much Infergen to use, how to inject it, how often to inject, and how to dispose of the syringes, needles and left over amounts of Infergen. Your healthcare professional will train you and or the person that will be giving you the injections on the proper way to give injections. Whether you give yourself the injection or another person gives the injection to you, it is important that you are comfortable with how to prepare and inject a dose of Infergen, and you understand the instructions in "*How do I inject Infergen?*".

Infergen is a ready-to-use solution given three times a week as a single injection. Your doctor will determine the amount (your dose) you will inject. Do not change your dose unless your doctor tells you to change it. It is important that you take Infergen exactly as your doctor tells you. The dose your doctor prescribes will usually be measured in milliliters. It is important to use a syringe that is marked in tenths of milliliters (mLs), for example, 0.1 mL. Your doctor or nurse may refer to a mL as a cc (1 mL = 1 cc). Always use the correct syringe. Failure to use the right syringe can lead to a mistake in dosage; you may receive too little or too much Infergen. Too little Infergen may not be effective in treating your HCV infection and too much Infergen may cause side effects. If you take more than your prescribed amount, call your doctor right away. Your doctor may want to examine you.

Once you start treatment with Infergen, do not switch to another brand of interferon without talking to your doctor. Other interferons may not have the same effect on the treatment of your disease. Switching brands will also require a change in your dose.

You should inject your dose of Infergen at the same time of day. If you miss a dose, you should give yourself an injection as soon as you remember and then call your doctor. Do not take your next scheduled dose until you have been told by your healthcare professional what you should do.

You must get regular blood tests to help your healthcare professional check how the treatment is working and to check for side effects.

What should I avoid while taking Infergen?

Avoid becoming pregnant while taking Infergen. Infergen may cause harm to an unborn child or cause you to lose your baby (miscarry). Do not breastfeed your baby while taking Infergen.

What are the possible side effects of Infergen?

Possible, serious side effects include:

- **Mental health problems including depression and suicidal thoughts and attempts, blood problems, and body organ problems:** See “*What is the most important information I should know about Infergen*”. (p. 1)
- **Heart problems:** Some patients who have taken interferon have had chest pains, and very rarely a heart attack. Patients who already have heart disease could be at greatest risk. Tell your healthcare provider if you have or have had a heart problem in the past.
- **Autoimmune problems:** Some patients may develop a disease where the body's own immune system begins to attack itself (autoimmune disease) while taking Infergen. These diseases can include psoriasis or thyroid problems. In some patients who already have an autoimmune disease, the disease may worsen while taking Infergen.

Some of the common but less serious side effects with alpha interferons include:

- **Flu-like symptoms.** Most patients who take Infergen have “flu-like” symptoms such as headache, muscle aches, tiredness, chills and fever that usually lessen after the first few weeks of therapy. If you inject your Infergen dose at bedtime, you may be able to sleep through the symptoms. You may also take a fever and pain reducer such as acetaminophen or ibuprofen, to help relieve or reduce the flu-like symptoms.
- **Fatigue (tiredness).** Many patients become extremely tired while on Infergen.
- **Upset stomach.** Nausea, loss of appetite, diarrhea and weight loss may occur.
- **Blood sugar problems.** Some patients develop problems with the way their body controls their blood sugar and may develop high blood sugar or diabetes.
- **Skin reactions.** Some patients have developed redness, rash, itching, lump, swelling, or bruising that does not go away at the site of injection. If, these symptoms do not disappear after several days, tell your doctor.
- **Hair thinning.** Some patients have experienced hair thinning during Infergen treatment but, hair loss stops and hair growth returns after you stop taking Infergen.

These are not all of the side effects of Infergen. Your doctor, nurse or pharmacist can give you a more complete list that has all the side effects.

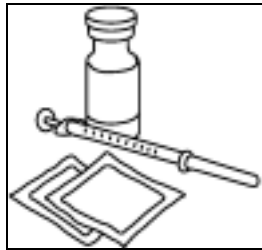
If you are worried about side effects or find them troublesome, you should talk to your healthcare professional.

How do I prepare and inject the Infergen dose?

Find a clean, comfortable, well-lit place and remove a vial of Infergen from the refrigerator and allow it to reach room temperature.

1. Assemble the supplies you will need for your injection:

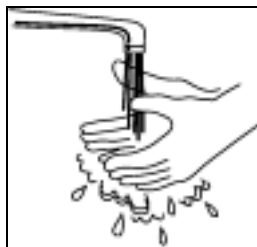
- A vial of Infergen
- One sterile disposable syringe and needle
- Several alcohol swabs and
- A puncture-proof container to dispose of the needle and syringe when you are done



2. Check the date on the vial of Infergen and make sure that the date has not passed and look at the liquid inside the vial.

- Do not use the Infergen if:
 - The liquid is cloudy
 - The liquid is not clear and colorless
 - The liquid has particles
 - The expiration date has passed

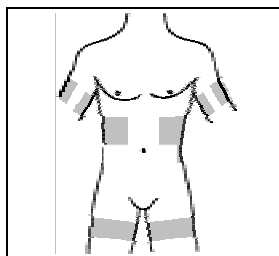
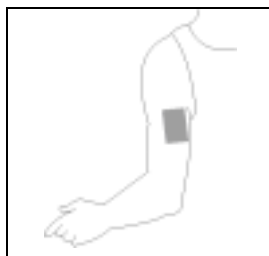
3. Wash your hands thoroughly with soap and water.



Select and prepare the injection site on your body

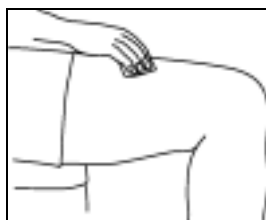
4. Pick a site for your injection.

- Back of the upper arms (if someone is giving you the injection)
- Abdomen, except for the navel and waist
- Upper thighs



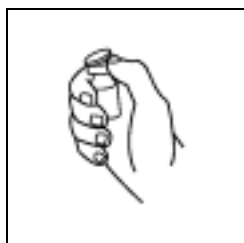
You should change the site for injection each time you inject to avoid soreness at any one site.

5. Clean the injection site with an alcohol swab. Use circular motions from the inside to the outside. Keep the used alcohol swab nearby.



Preparing the dose

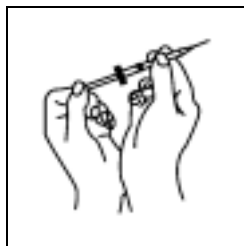
6. Remove the colored cap from the vial, exposing the rubber stopper.



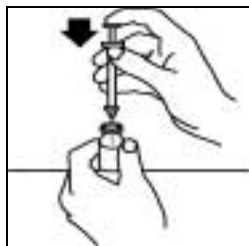
7. Clean the rubber stopper with a new alcohol swab, then cover the stopper with the swab.



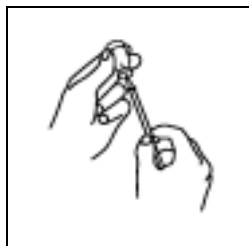
8. Remove the syringe and needle from their packages. If either package looks like they have been opened or damaged, do not use the syringe or needle; dispose of it in the puncture-proof disposal container.
9. Remove the needle cover and pull back the plunger and draw air into the syringe. The amount of air you draw into the syringe should be the same amount as the dose of medication your doctor has prescribed.



10. Remove the alcohol wipe from the top of the vial and insert the needle straight through the center of the rubber stopper.
11. Push the plunger of the syringe down to inject the air into the air space above the liquid in the vial. The air injected into the vial will allow Infergen to be easily withdrawn from the vial into the syringe.



12. Keeping the needle in the vial, turn the vial upside down and make sure that the tip of the needle is in the liquid.



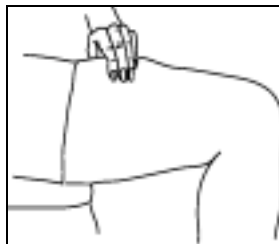
13. Slowly pull back on the plunger and let the medication enter the syringe, filling it to the line that equals the dose your doctor prescribed.
14. Keeping the needle in the vial, check for air bubbles in the syringe. Air bubbles are harmless but can reduce the dose you should be receiving. To remove the air bubbles, gently tap the syringe with your fingers until the bubbles rise to the needle-end of the syringe barrel. Then push the plunger in to force the air out of the syringe.

Make sure the tip of the needle is in the liquid and slowly pull back on the plunger until the liquid in the syringe reaches the mark that correctly matches the amount of your dose.

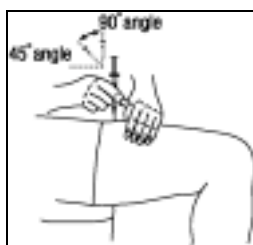
15. Take the needle out of the vial and hold the syringe needle facing up in the hand that you will use to inject yourself. Do not lay the syringe down or allow the needle to touch anything.

Injecting the dose

16. Use the other hand to pinch a fold of skin at the site you cleaned for an injection.



17. Hold the syringe the way you would hold a pencil and insert the needle either straight up and down (90 degree angle) or at a slight angle (45 degree angle) to the skin.



18. After the needle is in, let go of the skin. Pull the plunger back slightly. **If blood appears, do not inject Infergen, because the needle has entered a blood vessel.** Withdraw the syringe and discard it. Prepare a new syringe and inject at a new site. Repeat this procedure at the second site, checking for blood before injecting.
19. If no blood appears, slowly push down on the plunger all the way, until all the medication is gone from the syringe.



20. Pull the needle out of the skin at the same angle you put it in and place an alcohol swab over the injection site, then press for several seconds.



21. Promptly place the needle and syringe in the puncture proof disposal container. **Never reuse the syringe or needle. DO NOT RECAP THE NEEDLE.**

Disposal

Dispose of syringes and needles as directed by your doctor nurse or pharmacist. There may be special state and local laws.

Place all used needles, needle covers, and syringes in a special container called a “Sharps Container” or a hard plastic container, or a metal container with a plastic lid. Do not use glass or clear plastic containers, or any container that will allow the needles to stick through them.

Always keep the container out of the reach of children.

DO NOT recycle containers or throw full containers into the household trash.

How should I store Infergen?

Infergen should be stored in the refrigerator at 2° to 8°C (36° to 46°F), but not in the freezer compartment. Do not let Infergen freeze or leave it in direct sunlight. Do not use a vial of Infergen that has been frozen or past the expiration date stamped on the label. If you think that the Infergen has been frozen or left in direct sunlight, do not use it, and contact your doctor or nurse for further instructions. To transport Infergen, keep the product cool and avoid extreme temperature changes. Do not shake Infergen. If Infergen is shaken too hard, it will not work properly.

General advice about prescription medicines

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any concerns about Infergen, ask your doctor. Your doctor or pharmacist can give you information about Infergen that was written for health care professionals. Do not use Infergen for a condition for which it was not prescribed. Do not share this medication with other people.

Ingredients

Interferon alfacon-1 in a sterile, preservative-free solution of sodium chloride, sodium phosphate, and Water for Injection, USP.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

INTERMUNE

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